



AGENDA

15th Annual USFWS Aquaculture Drug Approval Coordination Workshop



June 09 – 11, 2009

Hosted by:

**U.S. Department of Agriculture, Agricultural Research Service –
Harry K. Dupree Stuttgart National Aquaculture Research Center (SNARC)**

Associated meetings:

- June 12, 2009:**
- National Aquaculture Drug Research Forum (NADRF)
 - Working Group for Aquaculture Chemicals (WGAC)
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Venue: [La Quinta Inn & Suites Downtown Conference Center](#); Little Rock, Arkansas, USA

Event Sponsors: [Arkansas Agriculture Department - Aquaculture Division](#), Arkansas Bait and Ornamental Fish Grower's Association, [Arkansas Catfish Promotion Board](#), [Aquatic Life Sciences](#), [B. L. Mitchell Inc.](#), [Bimeda](#), [Freeport-McMoRan Copper & Gold Inc.](#), [Frontier Scientific Inc.](#), [Intervet/Schering-Plough Animal Health Corp.](#), and [USDA/ARS Professional Activities grant](#)

Session moderators: [Jim Bowker](#), U.S. Fish & Wildlife Service – [Aquatic Animal Drug Approval Partnership Program](#) (USFWS/AADAP)

[Mark Gaikowski](#), U.S. Geological Survey [Upper Midwest Environmental Sciences Center](#) (USGS/UMESC)

[Dave Straus](#), U.S. Department of Agriculture/Agricultural Research Service, [Harry K. Dupree Stuttgart National Aquaculture Research Center](#) (USDA/ARS/SNARC)

Monday, June 08

- 1:00 – 3:00 pm** Tours of USDA's Stuttgart National Aquaculture Research Center (1.25 hr drive from hotel) available upon request. Contact Dave Straus or Cindy Ledbetter at 870-673-4483 to make arrangements. [Click here](#) for driving directions from hotel.
- 2:00 – 4:00pm** Early registration at the [La Quinta Conference Center](#), Room Bush 41
- 4:00 – 6:00pm** Early registration at [Vino's Pizza Pub & Brewery](#), 923 West 7th St. (5 blocks west)
- 4:00 – 8:00pm** Welcome Social at Vino's (*sponsored by:* Freeport-McMoRan Copper & Gold Inc.)



Tuesday, June 09 (La Quinta Conference Center – Grand Ballroom)

7:00 – 8:15am Workshop Registration

8:15 – 8:30am Welcome and Introduction

- [Dr. Don Freeman, Director – Harry K. Dupree Stuttgart National Aquaculture Research Center](#)

8:30 – 8:45am Welcome, housekeeping, agenda format, and extracurricular activities

- Dr. Dave Straus, USDA/ARS/SNARC

8:45 – 9:40am Agency Perspective

- [Dr. Jeff Silverstein, USDA/ARS National Program Leader – Aquaculture](#)
- [Dr. Beth Luddy, USFDA/CVM Deputy Director – Science Policy](#)
- Dr. Stuart Leon, USFWS
Chief, Division of Fisheries and Aquatic Resource Conservation
- [Jack Waide, USGS UMESC Deputy Center Director](#)
- Kevin Amos, NOAA Fisheries
National Aquatic Animal Health Coordinator

9:40 – 10:10am **Regional Aquaculture, Industry Perspective**

- Dr. Eric Park, President, Arkansas Bait and Ornamental Fish Grower's Association
Industry perspective
- [Wayne Branton, President, Catfish Farmers of Arkansas Industry perspective](#)
- [Dr. Carol Engle, University of Arkansas – Pine Bluff Fisheries and Aquaculture](#)

RECENT DRUG INDEX SUCCESS

10:10 – 10:15am **Ovaprim[®] and a surprise announcement**

[Western Chemical Inc. – Dr. Jim Brackett](#)

10:15 – 10:30am **BREAK** (*sponsored by: B.L. Mitchell Inc.*)

10:30 – 10:35am **DOOR PRIZE RAFFLE** (*sponsored by: Intervet/Schering Plough Animal Health*)

OVERVIEW PRESENTATIONS FROM CVM

10:35 – 10:50am [USFDA/CVM, Dr. Jennifer Matysczak – Update from CVM's Aquaculture Drugs Team](#)

10:50 – 11:05am [USFDA's MUMS Office, Dr. Dorothy Bailey – Indexing](#)

11:05 – 11:15am [USFDA/OR, Charles Gieseke – Update from FDA's Office of Research](#)



Tuesday, June 09 (continued)

THEMATIC PRESENTATIONS

11:15 – 11:30am Dr. Jesse Trushenski, SIU & AFS/FCS President Elect – USFWS-AFS partnership

11:30 – 11:45am Bonnie Johnson, USFWS/AADAP – USFWS National INAD Program overview

11:45 – 11:55am Steve Sharon, Chair, Drug Approval Working Group (DAWG) of the Association of Fish and Wildlife Agencies (AFWA) – AFWA perspective on aquaculture drug approvals for the public sector

11:55 – 12:05pm Roz Schnick, National Aquaculture NADA Coordinator perspective on all aquaculture drug approvals

12:05 – 1:30pm **LUNCH – on your own**

APPROVAL STATUS OF ORIGINAL AFWA PROJECT DRUGS (See Addendum for current and future approvals)

1:30 – 2:05pm **35% PEROX-AID®** (hydrogen peroxide)

- USFWS/AADAP, Jim Bowker – Expanding the label for 35% PEROX AID® - Control of mortality due to external columnaris in warmwater finfish - an update
- USGS/UMESC, Maren Tuttle-Lau – Efficacy of 35% PEROX AID® to reduce *Gyrodactylus* spp. infestation density on coaster brook trout *Salvelinus fontinalis* at the Iron River NFH
- USFWS/AADAP, Niccole Lawson – Expanding the 35% PEROX AID® label – an update
- Comments from Eka Chemical/ALS/Western Chemical, Status, and Discussion

2:05 – 2:40pm **HALAMID® AQUA** (chloramine-T)

- USFWS/AADAP, Jim Bowker – Chloramine-T - Control of mortality due to external columnaris in warmwater finfish - an update
- USGS/UMESC, Jeff Meinertz – Modification of the determinative method for p-TSA, the chloramine-T marker residue
- USFWS/AADAP, Jim Bowker – Chloramine-T white paper argument - an overview
- Western Chemical, Ron Malnor – Strategy to market
- Comments, discussion, and status

2:40 – 3:05pm **Triangle Brand Copper Sulfate®** (copper sulfate)

- USDA/ARS/SNARC, Dr. Dave Straus –Effectiveness and safety of copper sulfate to catfish eggs
- Comments from Freeport-McMoRan, status, and discussion

3:05 – 3:35pm **CAIROX®** (potassium permanganate)

- USDA/ARS/SNARC, Drew Mitchell – A challenge method for infecting fish with *Flavobacterium columnare* using high fish density and an ultra-low, flow-through water system



Tuesday, June 09 (continued)

- USDA/ARS/SNARC, Dr. Ahmed Darwish – Therapeutic assessment of potassium permanganate at early stages of experimental acute infection of *Flavobacterium columnare* in channel catfish (*Ictalurus punctatus*)
- USFWS/AADAP, Dr. Dave Erdahl – Potassium permanganate white paper
- USFWS/AADAP, Jim Bowker – Industry unmet label claim needs
- Comments, status, and discussion

3:35 – 3:50pm **BREAK** (sponsored by: Intervet/Schering Plough Animal Health)

3:50 – 3:55pm **DOOR PRIZE RAFFLE** (sponsored by: Intervet/Schering Plough Animal Health)

3:55 – 4:15pm **Formalin-F, Formacide-B, Paracide-F, and Parasite-S** (formalin)

- USFDA/OR, Charles Gieseke – Formalin treatment for saprolegnia infection in channel catfish
- Comments, status, and discussion

4:15 – 4:30pm **45 Years of Efforts toward Aquaculture Drug Approvals: A Perspective**

- Roz Schnick – National Aquaculture NADA Coordinator

4:30 – 4:35pm **DOOR PRIZE RAFFLE** (sponsored by: Frontier Scientific, Inc.)

5:30 – 8:00pm **Catfish Supper** – Transportation will be arranged. Located at the [Witt Stephens Jr. Central Arkansas Nature Center](#), River Market District, 602 Clinton Ave. (sponsored by: Arkansas Catfish Promotion Board)

Wednesday, June 10 (La Quinta Conference Center – Grand Ballroom)

APPROVAL STATUS OF ORIGINAL AFWA PROJECT DRUGS (CONTINUED)

8:00 – 9:10am **AQUAFLO[®]** (florfenicol)

- USFWS/AADAP, Bonnie Johnson – Florfenicol INAD #10-697 - Expanding use to 15 mg/kg fish body weight/day
- USGS/UMESC, Maren Tuttle-Lau – UMESC efforts to approve TM-200[®] or Aquaflor[®] to control motile aeromonad septicemia
- USFWS/AADAP, Jim Bowker – Aquaflor[®] medicated feed efficacy trial - Update
- USDA/ARS/SNARC, Cindy Ledbetter – Safety of Aquaflor[®] to sunshine bass: In-life phase
- USFWS/AADAP, Jim Bowker – Aquaflor[®] target animal safety study on yellow perch
- Idaho DF&G, Doug Munson – Control mortality of chinook salmon due to bacterial kidney disease – a planned study
- Comments from Intervet/Schering-Plough Animal Health, status, and discussion

9:10 – 9:30am **TERRAMYCIN[®] 200 For Fish** (oxytetracycline medicated feed)

- USFWS/AADAP, Dan Carty – Efficacy of TERRAMYCIN[®] 200 for Fish for the skeletal marking of rainbow trout
- Comments, status, and discussion



Wednesday, June 10 (continued)

NON-AFWA PROJECT DRUGS: THE OLD AND THE NEW

9:30 – 10:20am MASCULINIZING FEED FOR TILAPIA[®] (17 α -methyltestosterone)

- USFWS/AADAP, Dan Carty – 17MT efficacy technical section “complete” for tilapia
- National Aquaculture NADA Coordinator, Roz Schnick - Funding by NCRAC and WRAC for the analytical transfer and target animal safety study
- USGS/UMESC, Jeff Meinertz – Analytical 17 α -methyltestosterone feed method transfer study
- USDA/ARS/SNARC, Dr. Dave Straus –Target animal safety study and protocol development
- Auburn University, Dr. Ron Phelps – Environmental safety, update (presented by Dr. Tom Bell, USFWS/AADAP)
- USFWS/AADAP, Dr. Tom Bell – 17 α -methyltestosterone timeline
- Comments, status, and discussion

10:20 – 10:40am BREAK (sponsored by: Aquatic Life Science Inc.)

10:40 – 10:45am DOOR PRIZE RAFFLE (sponsored by: Intervet/Schering Plough Animal Health)

10:45 – 11:10am Porphyrins (AquaFrin[™]) – a novel photochemical technique for use as a microbicide

- USFWS/AADAP, Dr. Dave Erdahl – Compassionate INAD exemption and slaughter authorization
- Update from Frontier Scientific, Inc., Tim Miller
- Comments from Frontier Scientific, Inc., status, and discussion

11:10 – 11:30am Aquatic Life Sciences Inc., Dr. Jim Brackett - Overview of potential Aquatic Life Science, Inc. aquaculture products, SE-MARK[®] (calcein), OVAPRIM[®] (sGnRH α + additive injectable), OVAPLANT[®] (sGnRH α implant), and AQUACALM[®] (metomidate)

11:30 – 12:00pm AQUAMYCIN 100[®] (erythromycin)

- USGS/UMESC, Jeff Meinertz – Chronic toxicity of erythromycin thiocyanate to *Daphnia magna*
- USGS/UMESC, Mark Gaikowski – Overview of progress
- USGS/UMESC, Mark Gaikowski – Progress on the environmental assessment
- Comments, status, and discussion

12:00 – 1:30pm LUNCH – on your own

1:30 – 1:50pm SLICE[®] (emamectin benzoate in a 0.2% formulation)

- USFWS/AADAP, Dr. Dave Erdahl - SLICE[®] INAD update
- Comments from Intervet/Schering Plough Animal Health, status, and discussion



Wednesday, June 10 (continued)

1:50 – 3:15pm Sedatives

- AFWA, Steve Sharon – Status of immediate withdrawal sedatives: how we got from where we started to where we are now
- NOAA, Kevin Amos – Update of NOAA/Pacific NW sedative task force
- National Aquaculture NADA Coordinator, Roz Schnick – Update on all sedative needs and what we need to do to meet those needs
- USFWS/AADAP, Dr. Tom Bell – Status of benzocaine genotoxicity study
- USGS/UMESC, Jeff Meinertz – Status of eugenol total residue depletion study
- USFWS/AADAP, Dr. Dave Erdahl – Establishing INADs
- USGS/UMESC, Mark Gaikowski and Jeff Meinertz – Studies to evaluate the time to first feeding of fish after sedation
- USFWS/AADAP, Jim Bowker – Potential immediate release sedatives – here we go again
- Comments, status, and discussion

3:15 – 3:30pm BREAK (sponsored by: Intervet/Schering Plough Animal Health)

3:30 – 3:35pm DOOR PRIZE RAFFLE (sponsored by: Intervet/Schering Plough Animal Health)

3:35 – 4:30pm Use of Biologics in Aquaculture – Moderated by Craig Shoemaker

- The Flavobacterium challenge
- Question: What do fish fear? Answer: Streptococcus!

4:30 – 4:35pm DOOR PRIZE RAFFLE (sponsored by: Frontier Scientific, Inc.)

Thursday, June 11 (La Quinta Conference Center – Grand Ballroom)

8:00 – 8:45am CVM Presentations

- Aquaculture Drugs Team, Dr. Susan Storey – End Review Amendment (ERA) process
- Environmental Safety Team, Dr. Eric Silberhorn – Water quality benchmarks for aquaculture drugs: What, when, why and how
- Human Food Safety Division, Dr. Steve Yan – FDA's Guidance's #152 and #159: Similarities and differences

8:45 – 9:05am Regional Aquaculture, Industry Perspective

- Mike Freeze, Keo Fish Farm and NAA
- Joey Lowery, President, Catfish Farmers of America

9:05 – 9:50am Technical Presentations - General

- Dr. Alf Haukenes, University of Arkansas-Pine Bluff – Field trial evaluations of carp pituitary, catfish pituitary, and LHRHa at inducing ovulation in channel catfish



Thursday, June 11 (continued)

- Mark Gaikowski and Maren Tuttle-Lau, USGS/UMESC – An Evaluation of the efficacy of iodophor disinfection of walleye *Sander vitreum* and northern pike *Esox lucius* to control viral hemorrhagic septicemia virus
- Charles Giesecker, USFDA/OR – A survey of drug effects on a renal monogenean *in vitro*

9:50 – 10:05am **BREAK** (sponsored by: Bimeda and B.L. Mitchell, Inc.)

10:05 – 10:10am **DOOR PRIZE RAFFLE** (sponsored by: Intervet/Schering Plough Animal Health)

10:10 – 11:25am **Technical Presentations - Ectoparasites**

- Dr. Thomas Meinelt, Leibniz-Institute of Freshwater Ecology and Inland Fisheries – Peracetic acid, an alternative to fight fish ectoparasites!?
- Mark Gaikowski and Maren Tuttle-Lau, USGS/UMESC – Parasite-related aquatic animal health issues
- Dan Carty, USFWS/AADAP – In pursuit of label claims for the control of fish parasites with emphasis on the importance of parasite enumeration, an overview of a presentation by Sarah L. Poynton, Ph.D. (Associate Professor of Molecular and Comparative Pathology, The John Hopkins University School of Medicine, Baltimore)
- Drew Mitchell, USDA/ARS/SNARC – Parasite assessment and fish survival: Tools for the evaluation of copper sulfate and potassium permanganate tank treatments for Ichthyobodosis on sunshine bass
- Mark Gaikowski, USGS/UMESC and Todd Blessinger, FDA/CVM, Biometrics Team – Treatment efficacy protocol development

11:25 – 11:30am National Aquaculture Drug Research Forum

- Update
- Next scheduled meeting – Friday, June 12

11:30 – 11:35am Working Group for Aquaculture Chemicals

- Update
- Next scheduled meeting – Friday, June 12

11:35 – 12:00pm Wrap-up, plans for 16th Annual Aquaculture Drug Approval Coordination Workshop back in Bozeman, MT

1:00 – 7:00pm **Industry Tours** – Leave the La Quinta Conference Center at 1:00pm, transportation will be arranged. Tour includes visits to Anderson Minnow Farm, Pool Fisheries (ornamental fish), Hopper-Stevens Hatchery (catfish) and Keo Fish Farm (hybrid striped bass, grass carp, minnows, ornamentals, etc.). Crawfish-boil Supper will be held at Keo Fish Farm following the tour (sponsored by: USDA/ARS Professional Activities grant).

Friday, June 12 (La Quinta Conference Center – Room Bush 41)

8:00 – 10:15am National Aquaculture Drug Research Forum (NADRF) meeting

- See attached agenda - focus of meeting will be on study designs to evaluate treatments to control external parasites of fish

10:30 – 12:30pm Working Group for Aquaculture Chemicals (WGAC) meeting

- Agenda to be provided prior to meeting



ADDENDUM
to the Agenda for the
15th Annual USFWS Aquaculture Drug Approval Coordination Workshop

LABEL EXPANSIONS
See the [QUICK REFERENCE GUIDE](#) for all approved drugs and their uses

35% PEROX-AID®

FDA/CVM-approved:

- (1) For the control of mortality due to fungus of freshwater-reared finfish eggs
- (2) For the control of mortality due to bacterial gill disease of freshwater-reared salmonids
- (3) For the control of mortality due to external columnaris of coolwater finfish and channel catfish

Planned expanded label claim:

- (1) For the control of mortality due to external columnaris of freshwater-reared warmwater finfish
- (2) For the control of mortality due to saprolegniasis of all freshwater-reared finfish (except channel catfish)
- (3) For the control of certain ectoparasite infestations in freshwater-reared finfish

AQUAFLO®

FDA/CVM-approved (full and conditional approvals):

- (1) For the control of mortality due to enteric septicemia in catfish
- (2) For the control of mortality due to columnaris disease in catfish
- (3) For the control of mortality due to furunculosis in freshwater-reared salmonids
- (4) For the control of mortality due to coldwater disease in freshwater-reared salmonids

Planned expanded label claim:

- (1) For use to control mortality due to columnaris disease in all freshwater-reared salmonids
- (2) For use to control mortality due to *Streptococcus iniae* in hybrid striped bass and tilapia
- (3) For use to control mortality due to motile aeromonas disease in cool- and warmwater fish
- (4) For use to control mortality due to columnaris disease in cool- and warmwater fish
- (5) For use in freshwater-reared finfish at 15 mg florfenicol/kg body weight/d for 10 d

AquaFrin™

Initial approval (planned):

- (1) For use to control mortality due to saprolegniasis in freshwater-reared salmonids

AQUAMYCIN 100®

Initial approval (planned):

- (1) For use to control mortality due to bacterial kidney disease in all freshwater-reared salmonids

CAIROX®

Initial approval (planned):

- (1) For use to control mortality due to external columnaris in hybrid striped bass

Planned expanded label claim:

- (1) For use to control mortality due to external columnaris in channel catfish

Formalin-F, Paracide-F, Parasite-S, and Formacide-B

FDA/CVM-approved:

- (1) Control of external protozoa in all finfish
- (2) Control of monogenetic trematodes in all finfish
- (3) Control of protozoan parasites in penaeid shrimp
- (4) Control fungi of the family Saprolegniaceae in all finfish eggs

Planned expanded label claim:

- (1) For use to control mortality caused by saprolegniasis in all freshwater-reared finfish

HALAMID® AQUA+

Initial approval (planned):

- (1) For the control of mortality due to bacterial gill disease in all freshwater-reared salmonids
- (2) For the control of mortality due to external columnaris in walleye
- (3) For the control of mortality due to external columnaris of freshwater-reared warmwater finfish

Planned expanded label claim:

- (1) For the control of mortality due to external columnaris of freshwater-reared coolwater species

Triangle Brand Copper Sulfate®

Initial approval (planned):

- (1) For use to control mortality caused by Ich in catfish reared in earthen ponds

Planned expanded label claim:

- (1) For use to control mortality caused by fungus in channel catfish eggs in flow through systems

MASCULINIZING FEED FOR TILAPIA®

Initial approval (planned):

- (1) For use to produce predominantly male populations of tilapia

Planned expanded label claim:

- (1) For use to increase the proportion of phenotypic male swordtails
- (2) For use to produce phenotypic male rainbow trout

REWARD®

Initial approval (planned):

- (1) For use to control mortality in all freshwater-reared finfish caused by external columnaris
- (2) For use to control saprolegniasis in channel catfish eggs

SLICE®

Initial approval (planned):

- (1) For use to control mortality due to sea lice in cultured salmonids

Planned expanded label claim:

- (1) For use to control mortality due to external parasites in freshwater-reared finfish

TERRAMYCIN® 200 for Fish

FDA/CVM-approved:

- (1) For the control of bacterial hemorrhagic septicemia and pseudomonas disease in catfish
- (2) For the control of gaffkemia in lobster
- (3) For the control of ulcer disease, furunculosis, bacterial hemorrhagic septicemia, and pseudomonas disease in salmonids
- (4) For the control of mortality due to coldwater disease in freshwater-reared salmonids
- (5) For the control of mortality due to columnaris disease in all freshwater-reared *Oncorhynchus mykiss*
- (6) Mark skeletal tissue in Pacific salmon

Planned expanded label claim:

- (1) For control of mortality due to columnaris disease in all freshwater-reared salmonids
- (2) For control of mortality due to motile aeromonas disease in cool- and warmwater finfish
- (3) For use to mark skeletal tissue of all salmonids